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10/686,083	10/15/2003	Narayan Sundararajan	42P13833D	7275

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EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/686,083

Applicant(s)

SUNDARARAJAN ET AL.

Examiner

BJ Forman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: An Apparatus for Nucleic Acid Analysis.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1 and 4-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Allen (U.S. Patent No. 6,280,939, filed 1 September 1998).

Regarding Claim 1, Allen discloses an apparatus comprising an analysis chamber (cell #34), containing one or more structures (cantilever, #8), one or more reagent reservoirs in communication with the chamber (flow-through fluid chamber, #32) detection unit operably coupled to the structure (e.g. displacement sensor, #18), and data processing unit and control unit (computer, #14, Column 7, lines 25-29 and 45-52)(Column 7, lines 15-63 and Fig. 1).

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Regarding Claim 4, Allen disclose the apparatus wherein the structures are cantilevers (Column 7, lines 22-25).

Regarding Claim 5, Allen discloses the apparatus wherein the detection unit comprises a piezoelectric resistor (Column 7, lines 6-14).

Regarding Claim 6, Allen discloses the apparatus wherein the detection unit comprises a laser (Column 7, lines 6-14).

4. Claims 1 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindsay et al (U.S. Patent No. 5,750,989).

Regarding Claim 1, Lindsay et al disclose an apparatus comprising an analysis chamber (Fig. 8), containing one or more structures (scanning head, #104), one or more reagent reservoirs in communication with the chamber (tubes #114) detection unit operably coupled to the structure (e.g. STM/AFM), and data processing unit and control unit (Column 4, line 58-Column 4; Column 5, lines 56-67; Column 8, lines 14-55; and Column 15, lines 12-15).

Regarding Claim 4, Lindsay et al disclose the apparatus wherein the structures are cantilevers (Column 13, lines 8-22).

Regarding Claim 5, Lindsay et al disclose the apparatus wherein the detection unit comprises a piezoelectric resistor (Claim 1).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

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skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2-3 and 7-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Allen (U.S. Patent No. 6,280,939, filed 1 September 1998) in view of Colbert et al (WO 98/05920, published 12 February 1998).

Regarding Claim 2, Allen discloses an apparatus comprising an analysis chamber (cell #34), containing one or more structures (cantilever, #8), one or more reagent reservoirs in communication with the chamber (flow-through fluid chamber, #32) detection unit operably coupled to the structure (e.g. displacement sensor, #18), and data processing unit and control unit (computer, #14, Column 7, lines 25-29 and 45-52)(Column 7, lines 15-63 and Fig. 1). Allen teaches the apparatus wherein the chamber comprises nucleic acids and used for DNA sequencing (Abstract) but they do not teach nucleic acids attached to the cantilevers. However, Colbert et al teach a similar apparatus comprising a cantilever, detection unit and control unit (Fig. 1, 8 and page 6) and further teach modification of the cantilevers to use the probes as sensors and/or sample an interaction (page 21, line 20-page 22, line 17), the modification including attaching nucleic acids to the cantilever (page 24, lines 4-7).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cantilever of Allen by attaching nucleic acids as taught by Colbert et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success for the expected benefit of rapid molecular-level screening assays as desired in the art (Colbert et al, page 21, line 20-page 22, line 6).

Regarding Claim 3, Allen teaches the chamber comprising one or more polymerases (#50, Column 7, lines 64-67).

Regarding Claim 7, Allen discloses the apparatus wherein the detection unit detects changes in surface stress i.e. local force (Abstract and Column 4, lines 28-50)

Regarding Claim 8, Allen discloses an apparatus comprising an analysis chamber (cell #34), containing one or more structures (cantilever, #8), one or more reagent reservoirs in

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communication with the chamber (flow-through fluid chamber, #32) detection unit operably coupled to the structure (e.g. displacement sensor, #18), and data processing unit and control unit (computer, #14, Column 7, lines 25-29 and 45-52)(Column 7, lines 15-63 and Fig. 1).

Allen teaches the apparatus wherein the chamber comprises nucleic acids and used for DNA sequencing (Abstract) but they do not teach nucleic acids attached to the cantilevers.

However, Colbert et al teach a similar apparatus comprising a cantilever, detection unit and control unit (Fig. 1, 8 and page 6) and further teach modification of the cantilevers to use the probes as sensors and/or sample an interaction (page 21, line 20-page 22, line 17), the modification including attaching nucleic acids to the cantilever (page 24, lines 4-7).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cantilever of Allen by attaching nucleic acids as taught by Colbert et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success for the expected benefit of rapid molecular-level screening assays as desired in the art (Colbert et al, page 21, line 20-page 22, line 6).

Regarding Claim 9, Allen discloses the apparatus further comprising an information processing and control system (e.g. feedback computer control, Column 7, lines 41-52).

Regarding Claim 10, Allen discloses the apparatus wherein the information processing and control system is a computer (Column 7, lines 41-52).

Regarding Claim 11, Allen discloses the apparatus wherein the detection unit comprises a laser and position sensitive photodetector (Column 7, lines 6-9).

Regarding Claim 12, Allen discloses the apparatus wherein the detection unit comprises a piezoelectric resistor (Column 7, lines 6-14).

Regarding Claim 13, Allen discloses the apparatus wherein the template about 10 to 100,000 nucleotides (as illustrated in Fig. 1, 3 and 5).

Regarding Claims 14-15, Allen teaches the cantilever associated with the same molecule for sequence (Fig.1) but does not teach an array of cantilevers. Colbert et al teach the similar

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apparatus comprising an array of cantilevers associated with the same or different molecules i.e. homogeneous or heterogeneous (Fig. 8-9 page 39, lines 15-23) wherein the molecular association is designed according to intended use (page 39, lines 15-16). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the homogeneous or heterogeneous cantilever arrays of Colbert et al to the DNA sequencing cantilever of Allen. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success and for the expected benefit of use-specific apparatus wherein the use is determined based on DNA to be sequences.

Regarding Claim 16, Allen discloses an apparatus comprising an analysis chamber (cell #34), containing one or more structures (cantilever, #8), one or more reagent reservoirs in communication with the chamber (flow-through fluid chamber, #32) detection unit operably coupled to the structure (wherein the detection unit comprises a piezoelectric resistor (Column 7, lines 6-14), and data processing unit and control unit (computer, #14, Column 7, lines 25-29 and 45-52)(Column 7, lines 15-63 and Fig. 1).

Allen teaches the apparatus wherein the chamber comprises nucleic acids and used for DNA sequencing (Abstract) but they do not teach nucleic acids attached to the cantilevers. However, Colbert et al teach a similar apparatus comprising a cantilever, detection unit and control unit (Fig. 1, 8 and page 6) and further teach modification of the cantilevers to use the probes as sensors and/or sample an interaction (page 21, line 20-page 22, line 17), the modification including attaching nucleic acids to the cantilever (page 24, lines 4-7).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cantilever of Allen by attaching nucleic acids as taught by Colbert et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success for the expected benefit of rapid molecular-level screening assays as desired in the art (Colbert et al, page 21, line 20-page 22, line 6).

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Regarding Claim 17, Allen discloses the apparatus further comprising a resistance measuring device (Column 7, lines 38-45).

Regarding Claim 18, Allen discloses the apparatus wherein the template about 10 to 100,000 nucleotides (as illustrated in Fig. 1, 3 and 5).

Regarding Claim 19, Allen discloses an apparatus comprising an analysis chamber (cell #34), containing one or more structures coated with a substance (cantilever in solution, #8), one or more reagent reservoirs in communication with the chamber (flow-through fluid chamber, #32), polymerase in the chamber (#50) detection unit to detect deflection of the cantilever (e.g. displacement sensor, #18), and data processing unit and control unit (computer, #14, Column 7, lines 25-29 and 45-52)(Column 7, lines 15-63 and Fig. 1). Allen teaches the apparatus wherein the chamber comprises nucleic acids and used for DNA sequencing (Abstract) but they do not teach nucleic acids attached to the cantilevers. However, Colbert et al teach a similar apparatus comprising a cantilever, detection unit and control unit (Fig. 1, 8 and page 6) and further teach modification of the cantilevers to use the probes as sensors and/or sample an interaction (page 21, line 20-page 22, line 17), the modification including attaching nucleic acids to the cantilever (page 24, lines 4-7).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cantilever of Allen by attaching nucleic acids as taught by Colbert et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success for the expected benefit of rapid molecular-level screening assays as desired in the art (Colbert et al, page 21, line 20-page 22, line 6).

Regarding Claims 20-22, Allen teaches the apparatus wherein the cantilever is in contact with DNA and polymerase (Fig. 1) but does not teach coating the cantilever with an alloy (e.g. gold) or anchoring nucleic acids via a thiol group. However, Colbert et al teach the similar apparatus wherein the cantilevers are derivatized for attachment of biomolecules (page 22, lines 4-6). Colbert et al teach the preferred derivation comprises coating the cantilever

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with an alloy (e.g. gold) whereby thiol derivatized molecules are attached (page 39, lines 3-9). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the gold coating and thiol attachment of Colbert et al to the cantilevers of Allen. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success and for the expected benefit of molecular-level screening using preferred derivatized cantilevers as taught by Colbert et al (page 39, lines 3-9).

Double Patenting

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. Claims 1-22 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 24-46 of copending Application No. 10/705,389. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-17, 19-20, 29-30, 34-37, 42-52 of copending Application No. 10/254,201 in view of Lindsay et al (U.S. Patent No. 5,750,989).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an apparatus comprising cantilever structures, detection unit and data processing/control unit. The claims sets differ in the arrangement of limitations within the claims sets e.g. independent Claim of the '083 application is drawn to a cantilever and instant Claim 1 is drawn to a structure while dependent Claim 4 defines the structure as a cantilever. The claim sets merely differ in that the instant claims define the cantilever as part of an analysis chamber. While the '083 claims do not require a chamber, cantilevers chambers were well known and routinely practiced in the art at the time the claimed invention was made as taught by Lindsay et al who teach that the chamber permits sample analysis within a controlled environment (Column 4, lines 12-34). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the chamber of Lindsay et al to the '083 apparatus for the expected benefit of environmentally controlled sample analysis as desired in the art (Lindsay et al, Column 4, lines 12-34).

This is a provisional obviousness-type double patenting rejection.

11. No claim is allowed.

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Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
March 2, 2006